Remarks

I. Status of the Application and Claims

As originally filed, the present application had a total of 19 claims. All of these have now been canceled and new claims 20-30 have been introduced. An Office Action has been issued by the Patent Office in which all of Applicants' original claims were rejected.

II. The Amendments

New claims 20-30 were added. Support for these claims may be found as follows:

Support for new claim 20 may be found in original claim 1.

Support for claims 21-24 may be found on page 5 of the specification, lines 3- 9.

Support for new claim 25 may be found on page 25 of the application (first sequence in Sequence Listing) lines 21- 24, setting forth the coding region for SEQ ID NO:1.

Support for new claim 26 for a may be found in original claim 5.

Support for the new claims 27 and 28 may be found on page 10 of the specification, lines 5-32.

Support for new claims 29 and 30 and be found on page 10 of the application, lines 32-35 and on page 6, lines 4 - 19.

None of the amendments described above add new matter to the application and their entry is therefore respectfully requested.

III. Information Disclosure Statement

On page 2 of the Office Action, the Examiner alleges that the Information Disclosure Statement (IDS) filed by Applicants fails to comply with 37 CFR 1.98(a)(2). This is allegedly because the cited references were not included. Enclosed herewith as "Exhibit A" is a date-stamped receipt from the Patent Office indicating that the references were, in fact, included at

the time the previous IDS was filed. Nevertheless, as a courtesy to the Examiner, Applicants are resubmitting the references herewith. Since they were originally filed in a timely manner, Applicants do not believe that any fee should be required for the present submission.

The Rejections

I. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

On pages 2-4 of the Office Action, the Examiner rejects claims under 35 U.S.C. § 112, first paragraph. The grounds upon which this rejection is based are set forth in items 5 and 6. Below, Applicants reply to each allegation.

A. Response to Allegations in Item 5

In item 5, claims are rejected based upon the allegation that they fail to meet the written description requirement of patentability. It is alleged that the claims include all polynucleotides at least 70% identical to a polynucleotide encoding a protein at least 70% identical to SEQ ID NO:2. The Examiner argues that the specification does not provide any information concerning the function/activity relationship for the pfkA protein. Therefore, one of skill in the art would conclude that Applicants are not in possession of the claimed invention.

Applicants respectfully traverse this rejection.

First, it should be appreciated that the claims presently pending in the application are considerably narrower than the ones that were considered by the Examiner. The present claims are directed to polynucleotides encoding polypeptides at least 70% identical to SEQ ID NO:2 and which maintain essentially all of the phosphofructokinase enzymatic activity of the SEQ ID NO:2 protein.

Without question, at the time the present application was filed, the inventors had conceived of the *C. glutamicum* pfkA protein and the full length sequence of this protein is set forth in the application as SEQ ID NO:2. Moreover, its enzymatic activity was identified

and its ability to function in the bacterial production of amino acids was demonstrated. Based upon this knowledge, one of skill in the art can readily conceive of highly homologous counterparts that maintain the same activity. It is Applicants' position that claims such as those now pending, that include both a specific sequence and other sequences that are substantially the same in terms of structure and function, are not overly broad and should be patentable. If this was not the case and patentees were limited to the single species of protein disclosed in an application, claims to genes and proteins would be essentially worthless. It would be a trivial matter for a competitor to make minor changes in sequence to avoid infringement.

B. Response to Allegations in Item Number 6

In item 6, the Examiner rejects claims 1-7 based upon the enablement requirement of patentability. It is argued that one of ordinary skill in the art would not be able to make and use all of the polynucleotides claimed.

Applicants respectfully traverse this rejection.

The Examiner's argument appears to be that it would take undue experimentation for one of skill in the art to make and use all of the polynucleotides encompassed by the present claims. However, this is an improper standard for judging enablement. The relevant question is not whether one of skill in the art can make *all* of the embodiments but rather whether such an individual can make and use *each* embodiment without undue experimentation.

The synthesis of polynucleotides is routine in the art and there is no reason to think that the making of any of the polynucleotides encompassed by Applicants' claims would be unusually difficult. Similarly, recombinant DNA techniques for introducing genes into cells and the use of such cells for the making of amino acids are well known techniques and should not require undue experimentation. In the present case, this is should be all that is required of enablement.

To an extent, it appears that the Examiner may be more concerned with the requirements 35 U.S.C. § 112, second paragraph, *i.e.*, the Examiner seems to be alleging that one of skill in the art would not be able to tell whether any given polynucleotide falls within the scope of claims. However, it again appears that an inappropriate standard is being applied. There is no requirement that such a person be able define every member of a genus claim. Claims to chemical inventions often include millions of compounds and such an undertaking would clearly be impractical. The issue is whether a claim is sufficiently definite to allow one of skill in the art to determine whether any given, potentially infringing subject matter falls within its scope. In the present case, such an individual would only need to be able to do two things. First, they would need to be able to tell whether a potentially infringing polynucleotide encoded a protein and, if it did, whether the protein had a sequence at least 70% identical to the sequence of SEQ ID NO:2. This is a trivial undertaking and, in the vast majority of cases should settle the question of infringement. In cases where the polynucleotide encodes a protein that is highly homologous to SEQ ID NO:2, it might be necessary to carry out an assay to determine its biological activity. However methods of assessing phosphofructokinase activity are well known in the art and assays for determining effects on amino acid production by bacteria are described in the application. Moreover, such analysis would only involve two proteins, the one that is potentially infringing and the one defined by SEQ ID NO:2. Applicants therefore submit that the present claims provide sufficient information to determine the subject matter that they encompass and that all of this subject matter is fully enabled.

II. Rejection of Claims Under 35 U.S.C. §112, Second Paragraph

On pages 4 and 5 of the Office Action, claims are rejected under 35 U.S.C. § 112, second paragraph. The Examiner alleges that the phrase "70% to a polynucleotide which codes for a polypeptide" is indefinite because the sequence of the polypeptide is not defined. Although the specific phrase objected to by the Examiner is no longer present in the pending claims, they do refer to polynucleotides that encode proteins that are at least 70% identical to SEQ ID NO:2 and that maintain essentially full enzymatic activity.

The definiteness requirement of patentability is met if one of ordinary skill in the art, is able to distinguish the subject matter claimed from that in the prior art and that which may be discovered in the future. As discussed above, it would be a facile matter for a skilled molecular biologist to determine whether a polynucleotide encodes a protein sharing at least a 70% identity with the sequence of SEQ ID NO:2. Apart from this, the only other thing that might be required would be to, on occasion, use established assays to determine the extent to which highly homologous proteins have the same activity as the protein of SEQ ID NO:2. Applicants therefore submit that the present claims clearly meet the § 112, second paragraph requirements.

The Examiner also alleges that phrases referring to the "degeneration of the genetic code" and to "sense mutations of neutral function" are indefinite. In addition, it is alleged that claims that include polynucleotides based upon the way in which they hybridize are improper unless the conditions of hybridization are defined. Since none of the phrases which the Examiner finds to be objectionable are still present in the claims, Applicants submit that the Examiner's rejection has been obviated.

III. Rejection of Claims Under 35 U.S.C. § 102

On page 5 of the Office Action, the Examiner rejects claims 1-3 under 35 U.S.C. §102(b) as being anticipated by Oliver, *et al.* (accession no. Z99263). The rejection appears to be based upon portions of claims which encompass polynucleotides that have at least 15 successive bases corresponding to a recited sequence identification number. Since these portions of claims are no longer present, Applicants respectfully submit that the Examiner's rejection has been obviated.

Conclusion

In light of the amendments and discussion above, Applicants submit that all of the Examiner's rejections have been overcome. It is therefore respectfully requested that these rejections be withdrawn and that the claims presently pending in the application be allowed.

If, in the opinion of the Examiner, a phone call may help to expedite the prosecution of this application, the Examiner is invited to call Applicants' undersigned attorney at (703) 905-2173.

Respectfully submitted,

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Date: April 15, 2002

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